

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
 )  
James D. Thacker ) Group Art Unit: To Be Assigned  
 ) (Parent Group Art Unit: 1645)  
Application Number: To Be Assigned ) Examiner: To Be Assigned  
 ) (Parent Examiner: P. Baskar)  
Filed: December 19, 2001 )  
 )  
For: METHODS FOR THE RAPID DETECTION OF ACTIVELY RESPIRING  
MICROORGANISMS (as amended)

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to the examination on the merits, please amend the above-captioned patent application as set forth in the Amendments below.

IN THE TITLE:

Please delete the original title in its entirety and substitute the following as a new title:

--METHODS FOR THE RAPID DETECTION OF ACTIVELY RESPIRING  
MICROORGANISM--.

IN THE SPECIFICATION:

**Please replace the first paragraph on page 1 of the specification with the following:**

--This application is a divisional of application serial no. 09/148,491 filed September 4, 1998, which is based on U.S. provisional application 60/057,657, entitled "A New Method for the Rapid Detection and Enumeration of Total Viable Bacteria and Species Typing," filed September 5, 1997.--

IN THE CLAIMS:

Please cancel claims 2, 4, 20 and 21 without prejudice or disclaimer.

IN THE ABSTRACT

Please delete the original abstract in its entirety and substitute the following as a new Abstract:

--A method for the rapid detection of actively respiring microorganisms comprises the steps of detecting the presence of microorganisms utilizing microbial enzymatic conversion of tetrazolium salts to formazan products, detecting the presence of formazan product.—

Please replace the current Abstract with the attached sheet containing the above Abstract.

REMARKS

By the foregoing, claims 1, 3, 5-19, 22-24 are pending, and claims 2, 4, 20 and 21 have been canceled without prejudice or disclaimer. The claims are supported by the original specification and claims. An Office Action on the merits is now awaited. Should there be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Applicant respectfully requests that these amendments be entered in the subject application prior to examination.

Respectfully submitted,

HELLER EHRMAN WHITE & MCAULIFFE LLP

Date: December 19, 2001

By: 

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## METHODS FOR THE RAPID DETECTION OF ACTIVELY RESPIRING MICROORGANISMS

This application is a divisional of application serial no. 09/148,491 filed September 4, 1998, which is based on U.S. provisional application 60/057,657, entitled "A New  
5 Method for the Rapid Detection and Enumeration of Total Viable Bacteria and Species Typing,"  
filed September 5, 1997.

### **Background of the Invention**

#### 1. Field of the Invention

This invention is directed to the methods for rapid amplification and detection of  
10 actively respiring microorganisms. Such methods are useful in the detection of microbial  
contaminants in the environment, industrial systems, water purification systems, as well as  
clinical, food, cosmetic and pharmaceutical samples.

#### 2. Description of the Background

Many U.S. industrial and medical business sectors are at risk for economic loss  
15 from microbial contamination. The presence of microorganisms can have a negative impact on  
business efficiency and productivity. Many bacterial species implicated in human disease as well  
as those non-pathogenic species that adversely impact industrial processes are ubiquitous in  
aqueous environments of all types including lakes, rivers, ponds, industrial process waters and  
even potable water supplies. The total potential economic loss to the U.S. gross domestic product  
20 due to microbial contamination has been estimated to be \$1 - \$2 Trillion (THACO Corporation,  
Independent Market Research, 1993).

Three primary determinants for monitoring microorganism contamination in  
industrial processes are (i) determination of the quantity of microorganisms that are present, (ii)  
determination that there are no microorganisms present, and (iii) determination of the specific  
25 type (species) of microorganisms that are present.

The classical approach to determinants (i) and (ii) is to culture the sample in  
question in the presence of selective nutrients and microscopically examine a specimen after  
staining with specific reagents. Whereas this approach may be satisfactory for some definitive  
clinical examinations, it is necessary to provide rapid detection, enumeration and identification of  
30 microorganisms in industrial and other routine and non-routine medical examinations such as  
mass casualty or epidemic situations.

Modern methods for microorganism detection and enumeration have focused on  
the development of more sensitive methods of detecting microorganisms and

## ABSTRACT

A method for the rapid detection of actively respiring microorganisms comprises the steps of detecting the presence of microorganisms utilizing microbial enzymatic conversion of tetrazolium salts to formazan products, detecting the presence of formazan product.